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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,237	09/26/2001	David Ringshaw	PC9472B	9382
7590 03/24/2004				
Paul H. Ginsburg Pfizer Inc. 20th Floor 235 East 42nd Street New York, NY 10017-5755			EXAMINER OWENS JR, HOWARD V	
			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,237

Applicant(s)

RINGSHAW ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/12/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/12/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/2004 has been entered.

35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte*

Art Unit: 1623

Hall, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 19 recites the broad recitation “avermectin” and the claim also recites “5-oximino-22, 23-dihydro-25-cyclohexylavermectin B I monosaccharide” which is the narrower statement of the range/limitation. Accordingly, claim 20 is rejected as it fails to remedy the deficiency of the parent claim.

35 U.S.C. § 103

Applicant's arguments filed 12-17-03 have been fully considered but they are not persuasive. The rejection of claims 3-5, 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Loftsson, U.S. 5,472,954 in combination with Asato et al. (Asato), U.S. 4,886,829 is maintained for the reasons of record.

Claims 3-5 are drawn to a composition comprising at least one anthelmintically active compound which is an avermectin, milbemycin or compound of formula I complexed with at least one cyclodextrin.

Asato teaches the compound of formula I and also teaches that compounds of this formula are antihelmintic compounds which may be formulated in liquid or solid form for infestation in warm blooded animals and agriculture. However, Asato does not teach the combination of the antihelmintic compound with cyclodextrin.

Loftsson bridges the nexus for the use of cyclodextrin with antihelmintic compounds as it teaches that antihelmintic compounds—such as ivermectin, avermectin, and milbemycin--can complex with cyclodextrin (See column 8, lines 49 - 50) and that cyclodextrins have been used in the art to increase the stability of drugs and agrochemicals when complexed therewith (col.1-col.2). Loftsson also teaches that “solid pharmaceutical preparations, made, for example by removal of water from the above mentioned aqueous cyclodextrin polymer drug solutions, for example by lyophilization, are characterized by faster and more efficient dissolution of drugs compared to the dissolution of drugs from solid cyclodextrin preparations without polymers. This can lead to hastening the onset of the therapeutic response and can also increase the total bioavailability of drugs from solid pharmaceutical preparations (col. 15, lines 43-51).”

Art Unit: 1623

Loftsson does not specifically teach the use of the compound of formula I with a cyclodextrin, however.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time of the invention to have complexed a cyclodextrin with an antihelmintic.

One of skill in the art would have been motivated to combine an antihelmintic with a cyclodextrin for the purpose of obtaining a complex with improved water solubility over the uncomplexed drug while maintaining the biological activity of said drug.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the case of the instant claims, the combination of an antihelmintic compound and cyclodextrin was gleaned from the prior art of Asato, not applicant's disclosure.

Applicant states that because the examiner stated the deficiency of Loftsson, the 35 burden for obviousness was not met. Applicant should note that if the Loftsson reference contained all of the elements of the claim, then a 35 U.S.C. 102 would be applicable. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the compounds are known, thus a reasonable motivation for the combination of the antihelmintic compound and cyclodextrin supported by the prior art was required. As cited *supra*, Loftsson bridges the nexus for the use of cyclodextrin with antihelmintic compounds as it teaches that antihelmintic compounds—such as ivermectin, avermectin, and milbemycin—can complex with cyclodextrin (See column 8, lines 49 - 50) and that

Art Unit: 1623

cyclodextrins have been used in the art to increase the stability of drugs and agrochemicals when complexed therewith (col.1-col.2). Applicant has not provided a response as to how the teachings of Loftsson with regard to the combination of the antihelminthic compound (such as those claimed) with cyclodextrin for increased stability is not a reasonable motivation; moreover, applicant's claim to superior results is not persuasive, given that the prior art of Loftsson previously recognized the increased stability of antihelminthic compounds when complexed with cyclodextrin over uncomplexed compounds.

Applicant argues that the examiner has applied an "obvious to try standard". An "obvious to try" standard is deemed impermissible in two situations: 1) where the prior art gives no indication as to which of numerous parameters are critical, or gives no indication as to which of many possible choices is likely to be successful; and 2) where the prior art gives only general guidance with respect to the form of the invention, but now how to achieve it in new areas of technology or in fields of experimentation which are seemingly promising. As set forth supra, the compound as an agrochemical has been taught in the prior art for complexing with cyclodextrin; moreover, the benefit of combining avermectins or milbemycins with cyclodextrin have been taught in the art, thus even assuming *arguendo* that the specific compound of formula I is not set forth in Asato, the use of this class of compounds with cyclodextrins is not a new area of technology or experimentation; thus the 35 U.S.C. 103 is not based on an improper "obvious to try standard".

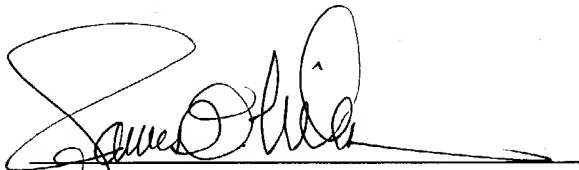
For the reasons cited supra, the rejection of record is maintained.

Application/Control Number: 09/963,237

Page 6

Art Unit: 1623

Howard V. Owens
Patent Examiner
Art Unit 1623

A handwritten signature in black ink, appearing to read "James O. Wilson", written over a horizontal line.

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.